

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application.

Listing of Claims:

1. 1-64. (canceled)

65. (previously presented) A pharmaceutically acceptable, sterile, micronized powder composition at least 98.5% by weight of which is pure budesonide or an ester, acetal or salt thereof.

66. (previously presented) The composition of claim 65, wherein at least 98.5% of the composition is pure budesonide.

67. (canceled)

68. (previously presented) The composition of claim 65, wherein at least 99% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

69. (previously presented) The composition of claim 65, wherein at least 99.2% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

70. (previously presented) The composition of claim 65, wherein the composition is in the form of particles having a mass median diameter (MMD) of less than 10 μm .

71. (previously presented) The composition of claim 70, wherein the particles have a MMD of less than 5 μm .

72. (previously presented) The composition of claim 70, wherein the particles have a MMD of less than 1 μm .

73. (previously presented) The composition of claim 70, wherein at least 99% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

74. (previously presented) The composition of claim 70, wherein at least 99.2% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

75. (previously presented) The composition of claim 65, wherein the composition is in the form of particles at least 80% of which have a MMD of less than 10 μm .

76. (previously presented) The composition of claim 75, wherein at least 99% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

77. (previously presented) The composition of claim 75, wherein at least 99.2% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

78. (previously presented) The composition of claim 75, wherein at least 70% of the particles have a MMD of less than 7 μm .

79. (previously presented) The composition of claim 78, wherein at least 99% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

80. (previously presented) The composition of claim 78, wherein at least 99.2% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

81. (previously presented) The composition of claim 75, wherein at least 60% of the particles have a MMD of less than 4 μm .

82. (previously presented) The composition of claim 81, wherein at least 99% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

83. (previously presented) The composition of claim 81, wherein at least 99.2% by weight of the composition is pure budesonide or an ester, acetal or salt thereof.

84. (previously presented) A pharmaceutically acceptable, sterilized powder composition at least 98.5% by weight of which is pure budesonide or an ester, acetal or salt thereof, wherein the sterilized powder composition was produced by sterilization of viable-microorganism-containing particles of budesonide or an ester, acetal or salt thereof.

85. (previously presented) The composition of claim 84, wherein at least 98.5% by weight of the composition is pure budesonide.

86. (previously presented) The composition of claim 84, at least 99% by weight of which is pure budesonide or an ester, acetal or salt thereof.

87. (previously presented) The composition of claim 84, at least 99.2% by weight of which is pure budesonide or an ester, acetal or salt thereof.

88. (previously presented) The composition of claim 87, wherein the sterilization was accomplished by a method comprising heat sterilization.

89. (previously presented) The composition of claim 88, wherein the heat sterilization was carried out in air.

90. (previously presented) The composition of claim 88, wherein the heat sterilization was carried out under an inert gas atmosphere.

91. (previously presented) The composition of claim 88, wherein the heat sterilization was accomplished at a temperature of 100 to 130°C.

92. (previously presented) The composition of claim 88, wherein the heat sterilization was accomplished at a temperature of 110 to 120°C.

93. (previously presented) The composition of claim 88, wherein the heat sterilization was accomplished at a temperature of 110°C.

94. (Currently amended) A sterile, pharmaceutically acceptable suspension consisting of the composition of claim 65 a micronized powder composition at least 98.5% by weight of which is pure budesonide or an ester, acetal or salt thereof, suspended in an aqueous solution.

95. (Currently amended) ~~A~~ The sterile, pharmaceutically acceptable suspension of claim 94, wherein at least 98.5% by weight of the micronized powder composition is pure budesonide. ~~consisting of the composition of claim 66 suspended in an aqueous solution.~~

96. (Currently amended) ~~A~~ The sterile, pharmaceutically acceptable suspension of claim 94, wherein at least 99% by weight of the micronized powder composition is pure budesonide or an ester, acetal or salt thereof. ~~consisting of the composition of claim 73 suspended in an aqueous solution.~~

97. (Currently amended) ~~A~~ The sterile, pharmaceutically acceptable suspension of claim 94, wherein at least 99.2% by weight of the micronized powder composition is pure

budesonide or an ester, acetal or salt thereof, consisting of the composition of claim 74
suspended in an aqueous solution.

98. (Currently amended) A sterile, pharmaceutically acceptable suspension consisting of a sterilized powder composition at least 98.5% by weight of which is pure budesonide or an ester acetal or salt thereof, the composition of claim 84 suspended in an aqueous solution, wherein the sterilized powder composition was produced by sterilization of viable-microorganism-containing particles of budesonide or an ester, acetal or salt thereof.

99. (Currently amended) ~~A~~The sterile, pharmaceutically acceptable suspension of claim 98, wherein at least 98.5% by weight of the powder composition is pure budesonide, consisting of the composition of claim 85 ~~suspended in an aqueous solution.~~

100. (Currently amended) ~~A~~The sterile, pharmaceutically acceptable suspension of claim 98, wherein at least 99% by weight of the powder composition is pure budesonide or an ester, acetal or salt thereof, consisting of the composition of claim 86 ~~suspended in an aqueous solution.~~

101. (previously presented) The suspension of claim 94, wherein one or more pharmaceutically acceptable ingredients selected from the group consisting of surfactants, pH regulating agents, chelating agents, agents that make the suspension isotonic, and thickening agents are dissolved in the aqueous solution.

102. (previously presented) The suspension of claim 101 comprising a surfactant that is a non-ionic surfactant, a sorbitan derivative, a polyoxyethylene ether, a polyoxyethylene castor oil derivative, or polyoxyethylene glycol, dissolved in the aqueous solution.

103. (previously presented) The suspension of claim 102, wherein the surfactant is present at about 0.002 to 2% w/w of the suspension.

104. (previously presented) The suspension of claim 102, wherein the surfactant is tyloxapol; polysorbate 80; or polyethylene glycol 660 hydroxystearate.

105. (previously presented) The suspension of claim 101 comprising a pH regulating agent that is a weak organic acid, mineral acid, strong alkaline agent or buffer.

106. (previously presented) The suspension of claim 105, wherein the pH regulating agent is citric acid, hydrochloric acid, NaOH, or sodium citrate.

107. (previously presented) The suspension of claim 105, wherein the suspension has a pH of about 3.5 to 6.0.

108. (previously presented) The suspension of claim 105, wherein the suspension has a pH of about 4.0 to 6.0.

109. (previously presented) The suspension of claim 105, wherein the suspension has a pH of about 4.2 to 4.8.

110. (previously presented) The suspension of claim 101, wherein a chelating agent is present at about 0.005 to 0.1% w/w of the suspension.

111. (previously presented) The suspension of claim 110, wherein the chelating agent is disodium edetate (EDTA).

112. (previously presented) The suspension of claim 101 comprising dextrose, glycerol, mannitol, or sodium chloride in an amount to make the solution isotonic.

113. (previously presented) The suspension of claim 101, wherein the aqueous solution comprises a thickening agent constituting about 0.1 to 3.0% w/w of the suspension.

114. (previously presented) The suspension of claim 113, wherein the thickening agent is ethyl cellulose, ethylmethylcellulose, cyclodextrin, dextrin, xanthan gum, providone, polyvinylprovidone (PVP) or polyethyleneglycol (PEG).

115. (previously presented) A method for the treatment of an inflammatory condition, the method comprising administering to a mammal suffering from such a condition a therapeutically effective amount of the composition of claim 65.

116. (previously presented) A method for the treatment of an inflammatory condition, the method comprising administering to a mammal suffering from such a condition a therapeutically effective amount of the composition of claim 66.

117. (previously presented) The method of claim 115, wherein the mammal is a human being.

118. (previously presented) A method for the treatment of chronic obstructive pulmonary disease (COPD), the method comprising administering to a mammal suffering from COPD a therapeutically effective amount of the composition of claim 65.

119. (previously presented) A method for the treatment of COPD, the method comprising administering to a mammal suffering from COPD a therapeutically effective amount of the composition of claim 66.

120. (previously presented) The method of claim 118, wherein the mammal is a human being.

121. (previously presented) A method for the treatment of rhinitis, the method comprising administering to a mammal suffering from rhinitis a therapeutically effective amount of the composition of claim 65.

122. (previously presented) A method for the treatment of rhinitis, the method comprising administering to a mammal suffering from rhinitis a therapeutically effective amount of the composition of claim 66.

123. (previously presented) The method of claim 121, wherein the mammal is a human being.

124. (previously presented) A method for the treatment of asthma, the method comprising administering to a mammal suffering from asthma a therapeutically effective amount of the composition of claim 65.

125. (previously presented) A method for the treatment of asthma, the method comprising administering to a mammal suffering from asthma a therapeutically effective amount of the composition of claim 66.

126. (previously presented) The method of claim 124, wherein the mammal is a human being.

127. (previously presented) A method for the treatment of an allergic condition, the method comprising administering to a mammal suffering from an allergic condition a therapeutically effective amount of the composition of claim 65.

128. (previously presented) A method for the treatment of an allergic condition, the method comprising administering to a mammal suffering from an allergic condition a therapeutically effective amount of the composition of claim 66.

129. (previously presented) The method of claim 127, wherein the mammal is a human being.

130. (previously presented) A method for the treatment of an inflammatory condition, the method comprising administering to a mammal suffering from such a condition a therapeutically effective amount of the suspension of claim 94.

131. (previously presented) A method for the treatment of an inflammatory condition, the method comprising administering to a mammal suffering from such a condition a therapeutically effective amount of the suspension of claim 95.

132. (previously presented) The method of claim 130, wherein the mammal is a human being.

133. (previously presented) A method for the treatment of COPD, the method comprising administering to a mammal suffering from COPD a therapeutically effective amount of the suspension of claim 94.

134. (previously presented) A method for the treatment of COPD, the method comprising administering to a mammal suffering from COPD a therapeutically effective amount of the suspension of claim 95.

135. (previously presented) The method of claim 133, wherein the mammal is a human being.

136. (previously presented) A method for the treatment of rhinitis, the method comprising administering to a mammal suffering from rhinitis a therapeutically effective amount of the suspension of claim 94.

137. (previously presented) A method for the treatment of rhinitis, the method comprising administering to a mammal suffering from rhinitis a therapeutically effective amount of the suspension of claim 95.

138. (previously presented) The method of claim 136, wherein the mammal is a human being.

139. (previously presented) A method for the treatment of asthma, the method comprising administering to a mammal suffering from asthma a therapeutically effective amount of the suspension of claim 94.

140. (previously presented) A method for the treatment of asthma, the method comprising administering to a mammal suffering from asthma a therapeutically effective amount of the suspension of claim 95.

141. (previously presented) The method of claim 139, wherein the mammal is a human being.

142. (previously presented) A method for the treatment of an allergic condition, the method comprising administering to a mammal suffering from an allergic condition a therapeutically effective amount of the suspension of claim 94.

143. (previously presented) A method for the treatment of an allergic condition, the method comprising administering to a mammal suffering from an allergic condition a therapeutically effective amount of the suspension of claim 95.

144. (previously presented) The method of claim 142, wherein the mammal is a human being.

145. (canceled)

146. (previously presented) A pharmaceutically acceptable sterilized composition in the form of finely divided particles of budesonide or an ester, acetal or salt thereof, the particles having a mass median diameter of less than 10 μm , wherein the sterilized composition was produced by dry-heat treatment of a viable-microorganism-containing powder of budesonide or an ester, acetal or salt thereof, at a temperature of from 100 to 130°C, thereby producing the sterilized composition.

147. (amended) A sterile powder composition prepared by a process comprising
(a) providing a powder composition comprising (i) particles of budesonide or an ester, acetal or salt thereof; and (ii) viable microorganisms, and containing less than about 1% (w/w) water, wherein the particles have a mass median diameter of less than 10 μm ; and
(b) heating the microorganism-containing powder composition at a temperature of from 100 to 130°C, thereby producing the sterile powder composition.

148. (previously presented) The composition of claim 65, wherein the budesonide is isomerically pure.

149. (previously presented) The composition of claim 148, wherein the budesonide is in the form of the (22R) diastereoisomer.

150. (previously presented) The composition of claim 84, wherein the budesonide is isomerically pure.

151. (previously presented) The composition of claim 150, wherein the budesonide is in the form of the (22R) diastereoisomer.

152. (previously presented) The method of claim 115, wherein the budesonide is isomerically pure.

153. (previously presented) The method of claim 152, wherein the budesonide is in the form of the (22R) diastereoisomer.

154. (previously presented) The composition of claim 146, wherein the budesonide is isomerically pure.

155. (previously presented) The composition of claim 154, wherein the budesonide is in the form of the (22R) diastereoisomer.

156. (previously presented) The composition of claim 147, wherein the budesonide is isomerically pure.

Applicant : Ann-Kristin Karlsson *et al.*
Serial No. : 09/993,669
Filed : November 27, 2001
Page : 14 of 25

Attorney's Docket No.: 06275-160002 / D 1863-1P US

157. (previously presented) The composition of claim 156, wherein the budesonide is in the form of the (22R) diastereoisomer.